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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,653	09/25/2003	Harry Eugene Flynn	KMG2010-US1	8371
65027 7590 06/07/2007 CHAPIN INTELLECTUAL PROPERTY LAW, LLC WESTBOROUGH OFFICE PARK 1700 WEST PARK DRIVE WESTBOROUGH, MA 01581			EXAMINER HOOK, JAMES F	
			ART UNIT 3754	PAPER NUMBER
			MAIL DATE 06/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	10/670,653	FLYNN ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1656	

All participants (applicant, applicant's representative, PTO personnel):

(1) Agnes B. Rooke.

(3) Amanda Murphy.

(2) Karen Carlson.

(4) David Forman and Hans-Peter Hauser.

Date of Interview: 29 May 2007.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: _____.

Claim(s) discussed: 10 and 19.


Identification of prior art discussed: See Continuation Sheet.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

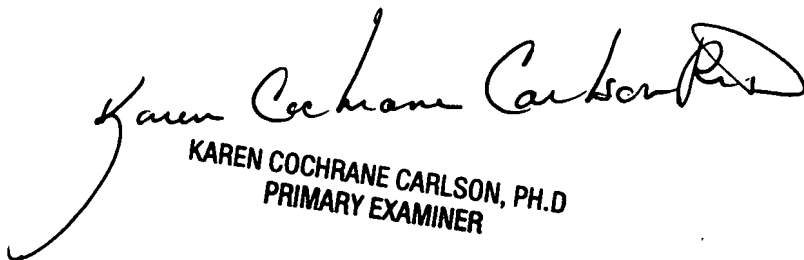
Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

During the interview, Applicants presented amendments to claims 10 and 19 (see copy of the amendments attached to this Interview Summary) that will overcome the outstanding rejection under the 35 USC 112, first paragraph, scope of enablement.

Also, during the interview, examiner provided a copy of the article by Kumpe et al. published in Arzneimittelforschung, 1981; 31(4):619-22. Examiner requested translation of the aforementioned article since the article is published in German (see copy of the Abstract as attached to this Interview Summary)..

AR


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

10. (Proposed Amendment) A process for producing a concentrate of a factor VIII:C-containing von Willebrand factor (vWF/FVIII:C), comprising subjecting a liquid comprising factor VIII:C (FVIII:C) and von Willebrand factor (vWF) to a fractional precipitation using an amino acid selected from glycine, α or β -alanine, α -, β - or γ -aminobutyric acid, lysine, valine, asparagine, and glutamic acid and an alkali metal salt or an alkaline earth metal salt, wherein the produced concentrate has an increased content of high molecular weight multimers of vWF, and wherein the concentrate has a ratio of von Willebrand factor ristocetin cofactor activity (vWF:RCoF) to von Willebrand factor antigen (vWF:Ag) of greater than 1.

19. (Proposed Amendment) The process as claimed in claim 10, further comprising prior to the fractional precipitation:

(a) mixing the liquid with an aluminum hydroxide suspension, stirring, and removing the prothrombin complex;

(b) precipitating fibrinogen with an amino acid selected from glycine, α or β -alanine, α -, β - or γ -aminobutyric acid, lysine, valine, asparagine, and glutamic acid and removing said fibrinogen; and

(c) precipitating the vWF/FVIII:C complex using an alkali metal salt or an alkaline earth metal salt.

Amanda Murphy

David Forman

Hans-Peter Hauser



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1: [Arzneimittelforschung. 1981;31\(4\):619-22.](#)

Links

[Factor VIII concentrate, highly purified and heated in solution (author's transl)]

[Article in German]

Heimburger N, Schwinn H, Gratz P, Luben G, Kumpe G, Herchenhan B.

A process is described to produce a highly purified factor VIII concentrate heated in solution. Pooled cryoprecipitate from citrated plasma is adsorbed on aluminum hydroxide gel. The fibrinogen is removed by heat denaturation in the presence of glycine; factor VIII is precipitated with sodium chloride from the supernatant. The precipitate is dissolved in a saccharose/glycine solution and heated at 60 degrees C for 10 h. The factor VIII is then separated by further precipitation with sodium chloride, the precipitate dissolved, dialysed and sterilized by filtration. The factor VIII concentrate contains approximately 6 units F VIII:C per mg protein. the ratio of F VIII R:Ag/F VIII:C is 3. The product is free from coagulable protein and gamma-globulins. The efficacy of the heating step in the reduction of the hepatitis B-infectious titre was proved in chimpanzees. For this purpose, hepatitis B virus was added to the pooled cryoprecipitate.

PMID: 6788045 [PubMed - indexed for MEDLINE]

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Severely heated therapeutic factor VIII concentrate of high specific activity. [Vox Sang. 1989]

Modified glycine precipitation technique for the preparation of factor VIII concentrate of high purity and high stability. [Vox Sang. 1987]

Development and small-scale production of a severely heated factor VIII concentrate. [Vox Sang. 1994]

Development of a heat-treated factor VIII/von Willebrand factor concentrate prepared from heparinized plasma. [Thromb Haemost. 1990]

Progress in purification of virus-inactivated factor VIII concentrates. Three generations of solvent/detergent treated plasma derivatives. [Arzneimittelforschung. 1989]

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